

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Offic**

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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/028,514	02/23/98	GORFIEN	S 0942.4110002

HM22/1223

**EXAMINER**

WARE, D

ART UNIT	PAPER NUMBER
1651	10

**DATE MAILED:** 12/23/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.  
09/028,514

Applicant(s)

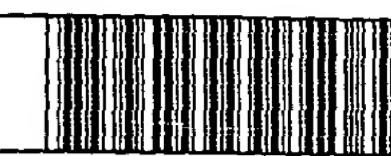
Gorlien et al.

Examiner

War

Group Art Unit

1651



Responsive to communication(s) filed on Sep 24, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 835 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-37, 73-83, 106-112, and 140-153 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-37, 73-83, 106-112, and 140-153 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) 08/920,875.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 & 7

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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Claims 1-37, 73-83, 106-112 and 140-153 are presented for examination on the merits.

The Information Disclosure Statements filed August 11, 1998 and September 24, 1999, respectively, have been received and the references submitted therewith have been considered as indicated on the enclosed PTO-1449 Forms.

The amendment filed September 24, 1999, has been received and entered.

1. Applicant's election without traverse of Group I (claims 1-37, 73-83 and 106-112) in Paper No. 9 is acknowledged. Furthermore, the cancellation of non-elected claims 38-47, 48-66, 67-72, 84-105 and 113-139 is acknowledged. However, although the election was made without traverse it should be noted that the restriction requirement is made **final** on the record.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-29, 79, 83 and 140-142 are rejected under 35 U.S.C. 102(b) as being anticipated by Israel, (U.S. Patent No. 5,318,898) cited on the enclosed copy of the PTO-1449 Form.

*Change 102(b)*

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Claims are drawn to a method of cultivating a mammalian cell in suspension by obtaining a mammalian cell and contacting the cell with a serum free medium comprising a polyanionic or polycationic compound.

Israel teaches a method of cultivating a mammalian cell in suspension by obtaining the cell and contacting with a serum free medium comprising dextran sulfate. The ingredients are inherent to the teachings of the reference in that the mammalian cells may be grown in any suitable medium such as MEM, DMEM, RPMI and various other media types. Further, Israel teaches the production of a polypeptide thereby and process therefore. The media disclosed by Israel are either taught to be protein free, chemically defined, and ingredients derived from non-animal sources; or the same is inherent to the disclosure since the reference teaches that the addition of animal-origin proteins presents the risk of contamination. Note the abstract and columns 1-4, all lines.

There appears to be no difference between what is claimed and what is taught by the cited reference. The claims are identical to the disclosure of Israel. Therefore, the claims are considered to be anticipated by the teachings of Israel.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israel, discussed above, in view of World Patent 92/05246, both cited on the enclosed PTO-1449 Forms.

The claims are further drawn to the different cell mammalian cell types that can be cultured using the claimed method.

Israel is discussed above and is drawn to CHO cell types.

However, the World Patent teaches that similar media types useful for CHO cell types can be used for human cells, kidney cells, etc., see page 3, lines 20-25.

The claimed subject matter differs from the disclosure of Israel in that the use of the media on other cell types other than CHO cells is not disclosed.

It would have been obvious to one of ordinary skill in the art to use the culture medium of Israel to culture other cell types such as human cells and kidney cells, etc. as taught by the World Patent. There would have been the motivation to use the cell culture medium of Israel to culture

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other mammalian cell types with an expectation of successful results. The claims are *prima facie* obvious over the cited prior art.

7. Claims 73-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israel in view of the World Patent, both discussed above, and Inlow et al., also cited on the enclosed PTO-1449 Forms.

Claims are drawn to a method of producing a virus using the method of claims 1, 15 or 22.

The method is taught above by the cited references of Israel and the World Patent. Inlow et al., teach the production of a virus using similar serum free medium. The claimed subject matter differs from the disclosure of Israel in that the reference was silent with respect to the production of virus.

It would have been obvious to one of ordinary skill in the art at the time of applicants' invention to use the culture medium of Israel, the World Patent, and Inlow et al. in order to produce a virus. The claims are *prima facie* obvious over the cited prior art.

8. Claims 78 and 83 are further rejected under 35 U.S.C. 102(b) as being anticipated by Inlow et al., cited and discussed above.

Claims are drawn to a virus and a polypeptide. Inlow et al. also teach a product virus and polypeptide (i.e. a recombinant product). Therefore, the claimed virus and polypeptide is identical to the disclosure of Inlow et al. in that

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there appears to be no difference between the claimed products and those disclosed in the prior art.

9. Claims 106 and 143-149 are rejected under 35 U.S.C. 102(b) as being anticipated by

Keen et al., also cited on the enclosed PTO-1449 Form.

*change do  
102 1103*

Claims are drawn to a method of cultivating mammalian cells in suspension culture.

Keen et al. teach an identical method of cultivating mammalian cells in suspension culture.

The claims are identical to the disclosure of Keen et al. and are, therefore, considered to be anticipated by the teachings of this cited reference.

10. Claims 150-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen et

al., discussed above.

*m*

These claims are drawn to culture media formulations and concentrations of iron and zinc ingredients in the media.

Keen et al. teach various culture media formulations and the iron and zinc component ingredients to also be contained by these formulations. Thus, it would have been well within the purview of one of skill to formulate specific components for use in the culture medium of Keen et al. Further, the disclosure of Keen et al. would have motivated one of skill in the art to provide for these media. Therefore, the claims are *prima facie* obvious over this cited reference.

11. Claims 106-112 and 143-153 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Keen et al. in view of Israel and Inlow et al, all cited on the enclosed PTO-1449 Forms and discussed above.

*154*

*155 156*

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The claimed subject matter differs from the disclosure of Keen et al. in that dextran sulfate nor the varied cell types that can be cultured are disclosed.

It would have been obvious to one of ordinary skill in the art at the time of applicants' invention to provide in the culturing process of Keen et al. dextran sulfate as disclosed by Israel and further to expect successful results for the growth of insect cells and expression of products thereby as taught by Inlow et al. All of the ingredients required by the claimed method and culture medium are disclosed in the combined cited prior art. Thus, the claims are rendered prima facie obvious.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

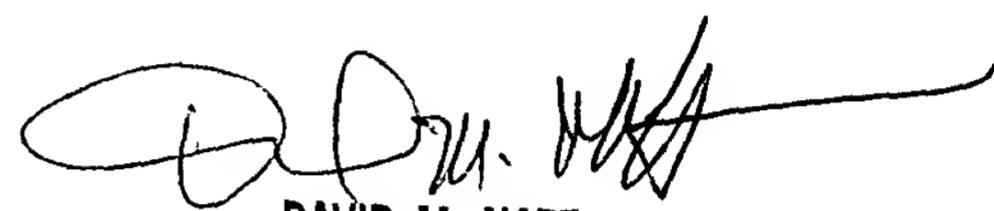
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Deborah K. Ware

December 18, 1999



DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 128